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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,528	09/02/2003	Brett P. Monia	ISPH-0769	3364

27180 7590 03/29/2006

ISIS PHARMACEUTICALS INC
1896 RUTHERFORD RD.
CARLSBAD, CA 92008

EXAMINER	
MCGARRY, SEAN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/653,528	MONIA ET AL.	
	Examiner	Art Unit	
	Sean R. McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/2/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: SEQ Alignment.

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 rejected under 35 U.S.C. 102(b) as being anticipated by Monia et al [US 6040,178].

Monia et al disclose SEQ ID NO: 37 which is an antisense oligonucleotide. Monia disclose all of the recited modifications to sugar, nucleobase and internucleoside backbone recited in the instant claims. Furthermore Monia et al disclose the use of the same recited carriers and diluents recited in the claims where the antisense SEQ ID NO: 37 of Monia et al is also disclosed as used in cells to inhibit expression of its target nucleic acid. SEQ ID NO: 37 comprises a local similarity of 94.1% oat the recited target region of claim 1. With this structure the oligonucleotide of SEQ ID NO: 37 meets all of the structural requirements of the instant invention (see age 14 of the instant specification for example). (See attached sequence alignment).

A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of

function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

**A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION,
AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE
APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE**

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

MPEP 2112.01:

PRODUCT AND APPARATUS CLAIMS X WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TOTHAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS AREPRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). AWhen the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.≅ *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

It is noted that SEQ ID NOS: 32, 33, and 37 where searched to facilitate the search of the target region recited in claim 1 and oligonucleotides that consist of these sequences are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sean R McGarry
Primary Examiner
Art Unit 1635

* ATTACHMENT NOT SEARCH NOTES

10/653,528

c 98	12.2	61.0	20	3	US-09-834-291-14	Sequence 14, Appl
c 99	12.2	61.0	22	3	US-08-884-029-3	Sequence 3, Appli
c 100	12.2	61.0	22	3	US-09-155-152-3	Sequence 3, Appli

ALIGNMENTS

RESULT 1
US-09-256-492-37
; Sequence 37, Application US/09256492
; Patent No. 6040178
; GENERAL INFORMATION:
; APPLICANT: Brett P. Monia
; APPLICANT: Lex M. Cowsert
; TITLE OF INVENTION: ANTISENSE MODULATION OF SMAD5 EXPRESSION
; FILE REFERENCE: RTS-0057
; CURRENT APPLICATION NUMBER: US/09/256,492
; CURRENT FILING DATE: 1999-02-23
; NUMBER OF SEQ ID NOS: 47
; SEQ ID NO 37
; LENGTH: 18
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Antisense Oligonucleotide
US-09-256-492-37

Query Match 77.0%; Score 15.4; DB 3; Length 18;
Best Local Similarity 94.1%; Pred. No. 9.1e+02;
Matches 16; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 4 AAAAGCTTCTTCAACAC 20
||||||||||.||||||
Db 2 AAAAGCTTCTCCAACAC 18

RESULT 2
US-08-495-209-25/c
; Sequence 25, Application US/08495209
; Patent No. 6476198
; GENERAL INFORMATION:
; APPLICANT: Kang, Angray S.
; TITLE OF INVENTION: Multispecific and Multivalent
; TITLE OF INVENTION: Antigen-Binding Polypeptide Molecules
; NUMBER OF SEQUENCES: 38
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: The Scripps Research Institute
; STREET: 10666 No. 6476198th Torrey Pines Road, TPC-8
; CITY: La Jolla
; STATE: California
; COUNTRY: US
; ZIP: 92037
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/495,209
; FILING DATE: 27-JUN-1995
; CLASSIFICATION: 530
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US 08/092,111
; FILING DATE: 13-JUL-1995
; ATTORNEY/AGENT INFORMATION:
; NAME: Fitting, Thomas
; REGISTRATION NUMBER: 34,163
; REFERENCE/DOCKET NUMBER: TSRI.305.1
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: 619-554-2937
; TELEFAX: 619-554-6312
; INFORMATION FOR SEQ ID NO: 25:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 45 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: DNA (genomic)
; HYPOTHETICAL: NO
; ANTI-SENSE: NO
US-08-495-209-25

Query Match 72.0%; Score 14.4; DB 3; Length 45;
Best Local Similarity 93.8%; Pred. No. 2.7e+03;
Matches 15; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 4 AAAAGCTTCTTCAACA 19
|| |||||||||||||
Db 45 AAGAGCTTCTTCAACA 30

RESULT 3
PCT-US96-10905-25/c
; Sequence 25, Application PC/TUS9610905
; GENERAL INFORMATION:
; APPLICANT: THE SCRIPPS RESEARCH INSTITUTE
; TITLE OF INVENTION: Multispecific and Multivalent
; TITLE OF INVENTION: Antigen-Binding Polypeptide Molecules
; NUMBER OF SEQUENCES: 38
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: PCT/US96/10905
; FILING DATE: 26-JUN-1996
; CLASSIFICATION:
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US 08/092,111
; FILING DATE: 13-JUL-1993
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US 08/495,209
; FILING DATE: 27-JUN-1995
; INFORMATION FOR SEQ ID NO: 25:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 45 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: DNA (genomic)
; HYPOTHETICAL: NO
; ANTI-SENSE: NO
PCT-US96-10905-25

Query Match 72.0%; Score 14.4; DB 6; Length 45;
Best Local Similarity 93.8%; Pred. No. 2.7e+03;
Matches 15; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 4 AAAAGCTTCTTCAACA 19
|| |||||||||||||
Db 45 AAGAGCTTCTTCAACA 30

RESULT 4
US-09-621-377B-21
; Sequence 21, Application US/09621377B
; Patent No. 6534643
; GENERAL INFORMATION:
; APPLICANT: EISEN, ANDREW
; TITLE OF INVENTION: DROSOPHILA RECOMBINATION-ASSOCIATED PROTEIN AND METHODS FOR USI
; FILE REFERENCE: 2567/1F496-US1
; CURRENT APPLICATION NUMBER: US/09/621,377B
; CURRENT FILING DATE: 2000-07-21
; PRIOR APPLICATION NUMBER: US 60/144,736